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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,454	01/02/2002	John S. Fisher	1139.16	6289

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15950 BAY VISTA DRIVE  
SUITE 220  
CLEARWATER, FL 33760

EXAMINER

MCCROSKY, DAVID J

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/683,454

Applicant(s)

FISHER ET AL.

Examiner

David J. McCrosky

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 24-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

This application contains claims directed to the following patentably distinct species of the claimed invention: Species A: a biopsy tool having a receptacle and filter (Figs. 1-6 and claims 1-23); Species B: a biopsy tool having a balloon (Figs. 7A-7E and claims 24 and 25); Species C: a biopsy tool having a cutting cannula (Figs. 8A-8D and claim 26); and Species D: a biopsy tool having an annular blade (Figs. 9A-10 and claims 27-32).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Ronald E. Smith on November 7, 2003 a provisional election was made without traverse to prosecute the invention of Species A, claims 1-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
It does not state that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the vacuum source, sinusoidal configured opening, sawtooth configured opening, flow tube mounted on an exterior surface and flow tube formed within the lumen must be shown or the features canceled from the claims. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities: "[T]he present Office practice is to insist that each claim must be the object of a sentence starting with 'I (or we) claim', 'The invention claimed is' (or the equivalent)". MPEP § 608.01(m). The last sentence of the specification should be corrected accordingly. Appropriate correction is required.

### ***Claim Objections***

Claims 1-23 are objected to because of the following informalities: brackets and parenthesis in the claims are reserved for drawing reference numbers; the brackets should be removed. The claims should be numbered in Arabic numerals only. See 37 CFR § 1.75(e). Claim 10 should depend from claim 9 to provide antecedent basis for "said irrigating means". In claim 14, "said motor means" lacks antecedent basis. It

appears that "removable" in line 1 of claim 23 should read --removably--. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7, 8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shuler in view of Alberico. Shuler discloses a hollow needle (14) with an inner tube (16) therein. The hollow needle (14) has a slot (88) that is in intermittent registration with an opening in the inner tube (18). Rotation means (54, 70) rotates the inner tube (16). See Figs. 1-3. A vacuum source pulls tissue into the slot. See col. 4, ll. 61-63 and col. 6, ll. 23-25. Shuler does not teach a needle with a pointed distal end. However, Alberico discloses a biopsy device having a hollow needle with a pointed

distal end. An inner tube rotates inside the hollow needle. See paragraphs 13-16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the needle of Shuler with a pointed distal end, as taught by Alberico, to minimize tissue damage.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shuler in view of Alberico as applied to claim 1 above, and further in view of Klein et al. Shuler and Alberico disclose a biopsy tool as recited for claim 1. The combination does not disclose a helical opening. However, Klein et al teach a biopsy tool having an inner and outer tube. The inner tube has a helical opening to aid in the capture of severed material. See col. 2, ll. 56-64 and col. 7, ll. 28-35. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the opening of Shuler and Alberico with the helical opening of Klein et al to aid in the capture of severed material.

Claims 3-6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shuler in view of Alberico as applied to claim 1 above. Shuler and Alberico disclose a biopsy tool as recited for claim 1. The combination does not disclose various opening configurations. It would have been an obvious matter of design choice to modify the opening of Shuler and Alberico by providing other configurations since Applicant has not disclosed that using the claimed configurations solves any stated problem or is for any particular purpose and it appears that the apparatus would perform equally well with any configuration, which aids in the collection of severed material.

Claims 9-14 and 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shuler in view of Alberico as applied to claim 1 above, and further in view of Turturro et al. Shuler and Alberico disclose a biopsy tool as recited for claim 1. The combination does not disclose an irrigating means or a receptacle with a filter trap. However, Turturro et al teach a biopsy tool having irrigation (24, 25) and aspiration means (26, 27). See Fig. 1 and col. 9, l. 56 to col. 10, l. 41. A receptacle with a removable filter trap is disclosed. See col. 3, l. 64 to col. 4, l. 13, col. 4, ll. 28-42 and col. 22, ll. 4-12. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the biopsy tool of Shuler and Alberico with the irrigation means and receptacle of Turturro et al to aid in aspirating and collecting the sample.

Regarding the functional "whereby" statements in claims 1 and 16, they do not define novelty in the structure and accordingly cannot serve to distinguish. *In re Mason*, 114 USPQ 127 (CCPA 1957)(functional statement cannot serve to distinguish claims, which are not process claims, from a reference since it does not define any structure).

### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Onik et al teach a biopsy tool with irrigation means formed between the inner and outer tubes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. McCrosky whose telephone number is 703-305-1331. The examiner can normally be reached on Mon-Fri 8:30-5:00.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

DJM

  
MAX F. HINDENBURG  
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